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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/597,813

04/13/2007

Ulrich Bogdahn

JCLA21512

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7590

04/01/2009

J C PATENTS, INC.  
4 VENTURE, SUITE 250  
IRVINE, CA 92618

EXAMINER

GIBBS, TERRA C

ART UNIT

PAPER NUMBER

1635

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/597,813	<b>Applicant(s)</b> BOGDAHN ET AL.	
	<b>Examiner</b> TERRA C. GIBBS	<b>Art Unit</b> 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This Office Action is a response to Applicant's Amendment and Remarks filed February 6, 2009.

Claims 19 and 22-25 have been amended.

Claims 19-25 are pending in the instant application.

Claims 19-25 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Nucleotide Sequence Disclosures***

In the previous Office Action mailed November 7, 2008, it was noted that the instant application failed to comply with the requirements of 37 C.F.R. §1.821-1.825 because pages 13, 17, and 36 of Applicant's disclosure contained sequences which fall under the purview of 37 CFR 1.821 through 1.825 as requiring SEQ ID NOs., but which are not so identified.

In response to this requirement, Applicants amended page 17 and 36 to comply with the sequence rules. However, Applicants contend that the sequences recited on page 13 are variants of SEQ ID NO:3 and thus are not presented as independent sequences and therefore do not need their own SEQ ID NO.

This response has been fully considered, but is not found persuasive because although the sequences recited on page 13 are variants of SEQ ID NO:3, they still require individual SEQ ID NOs. Applicant is reminded that 37 C.F.R. §1.821-1.825

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discloses:

(a) Nucleotide and/or amino acid sequences as used in §1.821 through 1.825 are interpreted to mean an unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides. Branched sequences are specifically excluded from this definition. Sequences with fewer than four specifically defined nucleotides or amino acids are specifically excluded from this section.

(b) Patent applications which contain disclosures of nucleotide and/or amino acid sequences, in accordance with the definition in paragraph (a) of this section, shall, with regard to the manner in which the nucleotide and/or amino acid sequences are presented and described, conform exclusively to the requirements of §1.821 through 1.825.

In view of this disclosure, the sequences recited on page 13 require their own SEQ ID NO. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

In the previous Office Action mailed November 7, 2008, claims 19-25 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This rejection is withdrawn** in view of Applicant's Amendment to the claims filed February 6, 2009. Specifically, the Examiner is withdrawing this rejection in view of Applicant's Amendment to the claims to spell out the term "TGF- $\beta$ R<sub>II</sub>".

In the previous Office Action mailed November 7, 2008, claims 19-25 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

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the invention. **This rejection is maintained** for the reasons of record set forth in the previous Office Action mailed November 7, 2008.

### ***Response to Arguments***

In response to this rejection, Applicants argue that claim 19 has been amended to provide more descriptions for clarification purposes and for correcting informalities. Applicants contend that in view of this amendment, the steps involved in the "use" claim are clearly recited.

Applicant's arguments have been fully considered, but are not found persuasive because the claim does not set forth any steps involved in the method/process, it is therefore unclear what method/process Applicant is intending to encompass. Applicant is reminded that a claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. It is noted that this rejection can be obviated by claiming "A method of" or "A process of", for example.

### ***Claim Rejections - 35 USC § 101***

In the previous Office Action mailed November 7, 2008, claims 19-25 were rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example, *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

**This rejection is maintained** for the reasons of record set forth in the previous Office Action mailed November 7, 2008.

### ***Response to Arguments***

In response to this rejection, Applicants argue that claim 19 has been amended to provide more descriptions for clarification purposes and for correcting informalities. Applicants contend that in view of this amendment, the steps involved in the "use" claim are clearly recited.

Applicant's arguments have been fully considered, but are not found persuasive because the claim does not set forth any steps involved in the method/process, it is therefore unclear what method/process Applicant is intending to encompass. Applicant is reminded that a claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. See for example, *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). It is noted that this rejection can be obviated by claiming "A method of" or "A process of", for example.

### ***Claim Rejections - 35 USC § 102***

In the previous Office Action mailed November 7, 2008, claims 19-25 were rejected under 35 USC 102(b) as being anticipated by WO 03/000656 A2. **This rejection is maintained** for the reasons of record set forth in the previous Office Action mailed November 7, 2008.

***Response to Arguments***

In response to this rejection, Applicants argue that claim 19 has been amended to provide more descriptions for clarification purposes and for correcting informalities. In view of this amendment, Applicants argue that Murray do not teach or suggest that the TGF- $\beta$ RII antisense oligonucleotides of their invention might be useful in treatment of neuronal disorders. Instead, Applicants contend that Murray merely teaches that the TGF- $\beta$ RII antisense oligonucleotides of their invention are used for treatment of diseases that are associated with TGF- $\beta$ RII expression, such as cancerous diseases or activation of the immune system. Applicants argue that Murray only shows that the antisense oligonucleotides of their invention affect the expression of TGF- $\beta$ RII in cell lines in cell culture and does not show that the effect of the antisense oligonucleotides to reduce expression of TGF- $\beta$ RII is connected to a real curative effect, as detailed in Applicant's invention.

This argument and contention have been fully considered, but are not found persuasive because it is noted that the claims recite an intended use, namely the promotion for successful regeneration and functional reconnection of damaged neural pathways in a mammal. Applicants argue that Murray does not teach or suggest such a use. Applicant is reminded that the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the functionality of the claim(s). Therefore, because the TGF- $\beta$ RII antisense

oligonucleotides of Murray are capable of promoting for successful regeneration and functional reconnection of damaged neural pathways in a mammal, they meet the claimed functionality and thus anticipate the claimed invention.

Therefore, absent evidence to the contrary, Murray anticipate claims 19-25.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached from 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James "Doug" Schultz can be reached on 571-272-0763. The fax phone



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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Terra Cotta Gibbs/  
March 26, 2009

/Sean R McGarry/  
Primary Examiner, Art Unit 1635